PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE CEIVED

FEB 0 4 2002

In re application of: Johnson et al.

Application No. 09/890,806

Filed: November 16, 2001

For: INHIBITION OF THE MHC **CLASS II ANTIGEN PRESENTATION** PATHWAY AND PRESENTATION TO

CD4+ CELLS

Examiner:

Date: January 7, 2002

Art Unit: 1645

TECH CENTER 1600/2900

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service on January 7, 2002 as First Class Mail in an envelope addressed to: COMINISSIONER

FOR PATENTS, WASHINGTON, D.C. 20231.

Panya M. Harding, Ph.D. Attorney for Applicant

INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. § 1.97(b)(3)

COMMISSIONER FOR PATENTS WASHINGTON, DC 20231

Sir:

Listed on the accompanying form PTO-1449 and enclosed herewith are several English-language documents. Applicants respectfully request that these documents be listed as references cited on the issued patent.

Applicants filed this Information Disclosure Statement ("IDS") before the mailing date of a first Office action on the merits. As a result, no fee should be required to file this IDS. However, if the Patent Office determines that a fee is required for Applicants to file this Information Disclosure Statement, please charge any such fees, or credit overpayment, to Deposit Account No. 02-4550. A duplicate copy of this Information Disclosure Statement is enclosed.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

One World Trade Center, Suite 1600

121 S.W. Salmon Street Portland, Oregon 97204 Telephone: (503) 226-7391

Facsimile: (503) 228-9446

Tanya M. Harding, Ph.D. Registration No. 42,630

RECEIVED

App: 07890 806 0 4 2002

App: 07890 806 1600/2900 Docket: 899-59399 FORMATION DISCLOSURE **STATEMENT** Applicant: Johnson et al.

BY APPLICANT

Filed: August 1, 2001 Art Unit: 1645

RK OFFICE	BY APPLICANT		Filed: August 1, 2001 Art Unit: 1643			
<u> </u>		U.S. PATE	ENT DOCUMENTS			
Init.* Number Date		Name	Class	Sub	Filed	
	5,202,426	Apr 13, 1993	Strumwasser et al.			
	5,529,774	Jun 25, 1996	Barba et al.			
	5,720,957	Feb 24, 1998	Jones et al.			
	5,750,398	May 12, 1998	Johnson et al.			
	5,843,458	Dec 1, 1998	Jones			
	5,908,780	June 1, 1999	Jones			
		FOREIGN PA	TENT DOCUMENTS	'		
Init.*	Number	Date	Country	Class	Sub	
	WO 97/32605	Sep 12, 1997	PCT			
1		ОТНЕ	R DOCUMENTS			
Init.*		Citation				
	sclerosi		interleukin 12 production in ivated CD4 ⁺ T cells via CD4 ⁰ uary 1997			
	histoco	asta et al., "Identification of an interferon- γ response region 5' of the human stocompatibility leukocyte antigen DR α chain gene which is active in human oblastoma multiform lines," J. Immunol. 138(4):1275-1280, February 15, 1987			man	
	Graft-V		C-Lymphocyte Precursor Free e in Bone Marrow Transplan			
			Sytomegalovirus Down-Regu he Stability of Class I H Chai			. <u></u>

EXAMINER:	DATE	
*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite		
if not in conformance and not considered. Send copy.		

151(9):4455-4464, November 1, 1993

WIII.JIO 01	70372002 899-3.	9399 02007.doc		TECE/
0		PION DISCI OCUPE	Docket: 899-59399	App: 09/290,806 B 0 4 2
INFORMATION DISCLOSURE STATEMENT			Applicant: Johnson et a	App: 09/290,806 B 0 4 20
ADEMARK OF	BY	APPLICANT	Filed: August 1, 2001	Art Unit: 1645
Init.*			Citation	
,	-	Berger et al., "T cell subsets immunodominant minor his 1102, April 15, 1994		
	_	Bradley et al., "HLA-DQB1 Severity of Collagen-induce 100(9):2227-2234, November	d Arthritis in Transgenic M	
		Bushell <i>et al.</i> , "Transplantat depleting anti-CD4 antibody induction phase of the response	depends on CD4 ⁺ T cell re	egulation during the
		Chirmule et al., "Role of E4 Adenovirus Vectors Deliver 72(7):6138-6145, July 1998	ed to Murine and Nonhuma	
	-	Cunha-Neto et al., "Autoima Myosin-B13 Trypanosoma of Lesions of a Chronic Chagas 1712, October 1996	cruzi Protein Crossreactive	T Cell Clones in Heart
		DeMatteo et al., "Immunolo transplantation," Transplant	-	
		Fleury et al., "Mutational And MHC: Class II Antigens Consite," Cell 66:1037-1049, Se	ntact CD4 on a Surface Opp	
		Gahéry-Ségard et al., "Phase Lung Cancer: Longitudinal S Viral Products," J. Clin. Inve	Study of the Immune Respo	onses to Transgene and
	_	Goldsmith <i>et al.</i> , "Infected C Neurovirulence by Blocking 348, February 2, 1998		
	-	González et al., "CD4 ⁺ cells e mice to induce neonatal tole	rance to alloantigens and a	

EXAMINER:	DATE		
*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite			
if not in conformance and not considered. Send copy.			

mice," Eur. J. Immunol. 25:1760-1764, 1995



FORMATION DISCLOSURE

STATEMENT

BY APPLICANT

App: 09/890,806 Docket: 899-59399

Applicant: Johnson et al.

Filed: August 1, 2001

Art Unit: 1645

Init.*	Citation
	Gossen et al., "Tight control of gene expression in mammalian cells by tetracycline-responsive promoters," Proc. Natl. Acad. Sci. USA 89:5547-551, June 1992
	Haskins and Wegmann, "Diabetogenic T-Cell Clones," Diabetes 45:1299-1305, October 1996
	Heath et al., "Protection Against Graft-Versus-Host Disease by Large Doses of Donor CD4 ⁺ T Cells: A Novel Approach to Bone Marrow Transplantation," Transplant. Proc. 25(1):1222-1224, February 1993
	Hemmer et al., "Cytokine Phenotype of Human Autoreactive T Cell Clones Specific for the Immunodominant Myelin Basic Protein Peptide (83-99)," J. Neuro. Res. 45:852-862, 1996
	Hill et al., "Herpes simplex virus turns off the TAP to evade host immunity," Nature 375:411-415, June 1, 1995
	Hitt et al., "Techniques for Human Adenovirus Vector Construction and Characterization," Meth. Mol. Gen. 7:13-30, 1995
	Jones et al., "Multiple Independent Loci within the Human Cytomegalovirus Unique Short Region Down-Regulate Expression of Major Histocompatibility Complex Class I Heavy Chains," J. Virol. 69(8):4830-4841, August 1995
	Korngold, "Lethal graft-versus-host disease in mice directed to multiple minor histocompatibility antigens: features of CD8 + and CD4 + T cell responses," <i>Bone Marrow Transplant</i> . 9:355-364, 1992
	Krieger et al., "Prolongation of Cardiac Graft Survival with Anti-CD4Ig Plus hCTLA4Ig in Primates," J. Surg. Res. 76:174-178, 1998
	Kusugami et al., "Loss of Interleukin-2Producing Intestinal CD4+ T Cells in Inflammatory Bowel Disease," Gastroenterology 101(6):1594-1605, 1991

EXAMINER:	DATE	
*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite		
if not in conformance and not considered. Send copy.		

- 1	ORMATION DISCLOSURE STATEMENT
5	0 1111 E//2E/ \ 1

Docket: 899-59399

App: 09/890,806

Applicant: Johnson et al.

Filed: August 1, 2001

Art Unit: 1645

REMARK OFFICE	
Init.*	Citation
	Lenschow et al., "Long-Term Survival of Xenogeneic Pancreatic Islet Grafts Induced by CTLA41g," Science 257:789-792, 7 August 1992
	Letterio et al., "Autoimmunity Associated with TGF-\(\beta\)1-Deficiency in Mice Is Dependent on HMC Class II Antigen Expression," J. Clin. Invest. 98(9):2109- 2119, November 1996
	Linsley et al., "Immunosuppression in Vivo by a Soluble Form of the CTLA-4 T Cell Activation Molecule," Science 257:792-795, 7 August 1992
	Lohse et al., "Lack of Requirement for CD8 ⁺ Cells in Recovery from and Resistance to Experimental Autoimmune Encephalomyelitis," J. Autoimmun. 8:395-404, 1995
	Martens et al., "Expansion of unusual CD4+ T cells in sever rheumatoid arthritis," Arthritis & Rheumatism 40(6):1106-1114, June 1997
	Massie et al., "Inducible Overexpression of a Toxic Protein by an Adenovirus Vector with a Tetracycline-Regulatable Expression Cassette," J. Virol. 72(3):2289-2296, March 1998
	McKnight et al., "Costimulator Dependence of Lymphokine Secretion By Naïve and Activated CD4 ⁺ T Lymphocytes From TCR Transgenic Mice," J. Immunol. 152:5220-5225, 1994
	Meinl et al., "Encephalitogenic Potential of Myelin Basic Protein-Specific T Cells Isolated from Normal Rhesus Macaques," Amer. J. Pathol. 150(2):445-453, February 1997
	Mosyak et al., "The Structure of HLA-DM, the Peptide Exchange Catalyst that Loads Antigen onto Class II MHC Molecules during Antigen Presentation," Immunity 9:377-383, September 1998
	Murphy et al., "B7 and Interleukin 12 Cooperate for Proliferation and Interferon γ Production by Mouse T Helper Clones That are Unresponsive to B7 Costimulation," J. Exp. Med. 180:223-231, July 1994

EXAMINER:	DATE	
*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite		
if not in conformance and not considered. Send copy.		

	0/2	<u>-</u>
10 4		DRMA
	3,	ST
\ <u>\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\</u>	100 5	
(Box	\ \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	BY.
No.	ARK OFFICE	

TION DISCLOSURE **CATEMENT**

APPLICANT

STATEMENT BY APPLICANT		Docket: 899-59399	App: 09/890,805	
		Applicant: Johnson et a	l. FER.O.	
		Filed: August 1, 2001	App: 09/890,800 FEB 0 4 Art Unit: TEOA CENTER 16	
it.*		Citation		
		of obesity and diabetes in ge Natl. Acad. Sci. USA 93:148		
	4	Analysis of the Binding Site Is 6-Phosphate Receptor," <i>J. 1</i>		
	virus by Cre-mediated exc	Parks et al., "A helper-dependent adenovirus vector system: Removal of helper virus by Cre-mediated excision of the viral packaging signal," <i>Proc. Natl. Acad. Sci. USA</i> 93:13565-13570, November 1996		
	. .	ntratracheal instillations of no onses and IFN-gamma produc		
		Numbers of in vivo Activated endent Diabetes Mellitus," J.		
		ansfer of Diabetesin the NOD Requirements for CD3 T-Cell		
	Influenced More by Proce	n of the Goodpasture Autoant ssing Constraints Than by HI m. 273(19):11440-11447, Ma	LA Class II Peptide Binding	
	Platt, "Xenotransplanting Medicine 3(1):26-27, Janu	hepatocytes: The triumph of ary 1997	a cup half full," Nature	
	in Renal Allograft Recipie	Monoclonal Antibody Therap ents-CD4 ⁺ T Cells Play an Ess c. 27(1):859-862, February	,	
	9	nt and Characterization of a N perimental Autoimmune Uve		

EXAMINER:	DATE	
*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite		
if not in conformance and not considered. Send copy.		

N.	FORMATION DISCLOSURE STATEMENT
n	STATEMENT

Docket: 899-59399 | App: 09/890,806

Applicant: Johnson et al.

Filed: August 1, 2001 Art Unit: 1645

RK OFFICE	Citation	
Init.*	Citation	
	Rudolph et al., "Gut-homing CD4 ⁺ T cell receptor αβ ⁺ T cells in the pathogenesis of murine inflammatory bowel disease," Eur. J. Immunol. 24:2803-2812, 1994	
	Sadlack <i>et al.</i> , "Generalized autoimmune disease in interleukin-2-deficient mice triggered by an uncontrolled activation and proliferation of CD4+ T cells," <i>Eur Immunol.</i> 25:3053-3059, 1995	
	Sanderson et al., "Association Between HLA-DM and HLA-DR In Vivo," Immunity 4:87-96, January 1996	
	Tak et al., "Reduction of synovial inflammation after anti-CD4 monoclonal antibody treatment in early rheumatoid arthritis," Arthritis & Rheumatism 38(10):1457-1465, October 1995	
	Tary-Lehmann <i>et al.</i> , "Induction of graft versus host-associated immunodeficiency by CD4+ T Cell Clones," <i>J. Immunol.</i> 145(7):2092-2098, October 1, 1990	
	Thivolet <i>et al.</i> , "CD8 ⁺ T cell homing to the pancreas in the nonobese diabetic mouse is CD4 ⁺ T cell-dependent," <i>J. Immunol.</i> 146(1):85-88, January 1, 1991	
	Thorsby and Røningen, "Role of HLA Genes in Predisposition to Develop Insulindependent Diabetes Mellitus," <i>Annals of Med.</i> 24:523-531, 1992	
	Tomazin et al., "Cytomegalovirus US2 destroys two components of the MHC class II pathway, preventing recognition by CD4 ⁺ T cells," <i>Nature Med.</i> 5(9):1039-1043, September 1999	
	Toyosaki et al., "Recognition of rheumatoid arthritis synovial antigen by CD4+, CD8- T cell clones established form rheumatoid arthritis joints," Arthritis * Rheumatism 41(1):92-100, January 1998	
	Tsuji et al., "Requirement of CD4 T Cells for Skin Graft Rejection Against Thymus Leukemia (TL) Antigen and Multiple Epitopes on the TL Molecule Recognized by CD4 T Cells," J. Immunol. 159:159-166, 1997	

EXAMINER:	DATE		
*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite			
if not in conformance and not considered. Send copy.			

NFORM	MATION DISCLOSURE
n	STATEMENT

Docket: 899-59399 | App: 09/890,806

Applicant: Johnson et al.

Filed: August 1, 2001 | Art Unit: 1645

, cy	Z				
HK OFFICE	,	Citation			
		Van Ginkel et al., "Adenoviral Gene Delivery Elicits Distinct Pulmonary-Associated T Helper Cell Responses to the Vector and to Its Transgene," J. Immunol. 159:685-693, 1997			
	~	VanBuskirk et al., "Acute rejection of cardiac allografts by noncytolytic CD4 ⁺ T cell populations," <i>Transplantation</i> 62(2):300-302, July 27, 1996			
	•	Vergelli <i>et al.</i> , "Human Autoreactive CD4 ⁺ T Cell Clones Use Perforin- or Fas/Fas Ligand-Mediated Pathways for Target Cell Lysis," <i>J. Immunol.</i> 158:2756-2761, 1997			
		Weimer et al., "Pretransplant CD4 helper function and interleukin 10 response predict risk of acute kidney graft rejection," Transplantation 62(11):1606-1614, December 15, 1996			
	-	Weston <i>et al.</i> , "Sequence of the short unique region, short repeats, and part of the long repeats of human Cytomegalovirus," <i>J. Mol. Biol.</i> 192:177-208, 1986			
	,	Wiertz et al., "The Human Cytomegalovirus US11 Gene Product Dislocates MHC Class I Heavy Chains from the Endoplasmic Reticulum to the Cytosol," Cell 84:769-779, March 8, 1996			
	·	Wiertz et al., "Sec61-mediated transfer of a membrane protein from the endoplasmic reticulum to the proteasome for destruction," <i>Nature</i> 384:432-438, December 5, 1996			
	-	Wubbolts et al., "MHC class II molecules: transport pathways for antigen presentation," Trends Cell Biology 7:115-118, March 1997			
		Yang et al., "Cellular immunity to viral antigens limits E1-deleted adenoviruses for gene therapy," Proc. Natl. Acad. Sci. USA 91:4407-4411, May 1994			
	~	Yang et al., "Immunology of gene therapy with adenoviral vectors in mouse skeletal muscle," Human Mol. Gen. 5(11):1703-1712, 1996			
L					

EXAMINER:	DATE	
*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite		
if not in conformance and not considered. Send copy.		

W(DRMATION DISCLOSURE
Γ	DRMATION DISCLOSURE STATEMENT

Docket: 899-59399 App: 09/890,806

Applicant: Johnson et al.

Filed: August 1, 2001 | Art Unit: 1645

2					
Init.		Citation			
	•	Yang et al., "Role of Viral Ar Adenovirus Vector-Transduce 7212, October 1996			
Yang et al., "Transient Subversion of CD40 Ligand Function Diminishes In Responses to Adenovirus Vectors in Mouse Liver and Lung Tissues," J. Vin 70(9):6370-6377, September 1996 York et al., "A Cytosolic Herpes Simplex Virus Protein Inhibits Antigen Presentation to CD8* T Lymphocytes," Cell 77:525-535, May 20, 1994					
			_		
	-	Zabner et al., "Adenovirus-Mediated Gene Transfer Transiently Corrects the Chloride Transport Defect in Nasal Epithelia of Patients with Cystic Fibrosis," Cell 75:207-216, October 22, 1993			
		Zelenika et al., "Rejection of Th1 and Th2 Cells: No Require 161:1868-1874, 1998			
	•	GenBank Accession No. P292 1992	241, ADP-Ribosyl Cyclase	e Precursor, December 1,	
		GenBank Accession No. P097	713, Hypothetical Protein	HQLF2, March 1, 1989	
	•	GenBank Accession No. QQE cytomegalovirus (strain AD16		cursor – human	
		L			

EXAMINER:	DATE	
*Examiner: Initial if considered, whether or not in conformance with MPEP 609; draw line through cite		
if not in conformance and not considered. Send copy.		